Research & Development
182 Susquehanna Ave
Exeter, PA 18643
570-655-5574
FAX 655-2990
www.pridemobility.com

K090805

Exhibit 1

510(k) Summary
Pride Mobility Products Corporation
V Series Scooters
Three and Four Wheel

APR - 3 2009

Submitter's Name & Address:
Pride Mobility Products Corporation
182 Susquehanna Avenue
Exeter, Pa. 18643
Phone: (570) 655-5574
Facsimile: (570) 655-2990

Contact Person:
Thomas Schappert
Official Correspondent

Date Prepared:
03-06-09

Name of Device and Proprietary Name:
V Series Scooters, Three and Four Wheel / Pride Mobility Products Corporation

Common or Usual Name:
Three and Four Wheel Power Scooter

Classification Name:
Physical Medicine / Motorized Three - Wheeled Vehicle

Product Code:
INI

Comparison to Predicate Devices:
The **V Series Scooters** are substantially equivalent to the Pride Mobility, Victory Three Wheel Scooter (K072165) and the Victory Four Wheel Scooter (K071949) when comparing, performance, maneuverability, stability, and structure. The performance characteristics and the position of the electronics and drive mechanisms are similar to achieve the same intended use function that enables the user to maintain optimum stability without hindering performance. The differences between The **V Series**

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Scooters to the Victory Three Wheel Scooter (K072165) and the Victory Four Wheel Scooter (K071949) are in the motors and control mechanisms.

Device Description:
The **V Series Scooters** are three and four wheeled battery-operated scooters. Features include a programmable controller, removable seat, a foldable tiller, two piece frame, and an off board charger; specific models include a Power Seat actuator. Additional safety features include electronic regenerative and electromechanical disc brakes, and rear anti-tip wheels. The Scooters can be disassembled into four parts: the rear section, the front section, batteries, and the seat; this allows for ease of use when traveling or storing the unit.
The **V Series Scooters** are designed with ultimate safety, stability, and performance in mind and are designed for, but not limited to Pride Mobility Products Corp. providers / retailers and their consumers.

Intended Use:
The intended use of the Pride Mobility Products Corp. V Series Scooters is to provide mobility to disabled persons having limited walking capabilities.

Non-Clinical Testing:
Compliance to applicable Testing Standards is as follows:
RESNA WC Vol.1 2008 DRAFT - Requirements and Test Methods for Wheelchairs (Including Scooters)
RESNA WC Vol. 2 2008 DRAFT - Additional Requirements for Wheelchairs (Including Scooters) with Electrical Systems
ANSI/RESNA WC Vol. 2-1998 Section 21 – Requirements and Test Methods for Electromagnetic Compatibility.
IEC 601-1-1 Medical Electrical Equipment, General Requirements for Safety
CAL 117 – Flammability Testing

Discussion of Clinical Testing Performed:
N/A

Conclusions:
The **V Series Scooters** have the same intended use and similar technological characteristics as the Victory Three Wheel Scooter (K072165) and Victory Four Wheel (K071949), moreover; the non-clinical testing and the predicate comparisons demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the V Series Scooters are substantially equivalent to the predicate devices, have passed all necessary testing, and are considered to be safe for user operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Pride Mobility Products Corporation
% Mr. Thomas Schappert
Official Correspondent
182 Susquehanna Avenue
Exeter, Pennsylvania 18643

APR - 3 2009

Re: K090805
Trade Name: V10, Three Wheel Scooter/Model # SC610V
V10, Three Wheel Scooter/Model # SC610VPS with Power Seat
V10, Four Wheel Scooter/Model # SC710V
V10, Four Wheel Scooter/Model # SC710VPS with Power Seat
Regulation Number: 21 CFR 890.3800
Regulation Name: Motorized three-wheeled vehicle
Regulatory Class: II
Product Code: INI
Dated: March 6, 2009
Received: March 25, 2009

Dear Mr. Schappert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit 3

Indications for Use

510(k) Number (if known): K

Device Name:

V10, Three Wheel Scooter / Model # SC610V
V10, Three Wheel Scooter / Model # SC610VPS with Power Seat
V10, Four Wheel Scooter / Model # SC710V
V10, Four Wheel Scooter / Model # SC710VPS with Power Seat

Indications for Use:

The intended use of the Pride Mobility Products Corporation V Series Scooters is to provide mobility to disabled persons having limited walking capabilities.

Prescription Use X **AND / OR** **Over-The-Counter Use** X
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K040808